K063120

510(k) Summary

as required by 807.92

NOV - 9 2006

1. Company Identification

EIZO NANAO CORPORATION
153 Shimokashiwano-cho, Hakusan-shi, Ishikawa-ken, 924-8566, Japan
Tel: +81-76-274-2468
Fax: +81-76-274-2484

2. Official Correspondent

Hiroaki Hashimoto (Mr.)
Manager of Engineering Management Section

3. Date of Submission

October 2nd, 2006

4. Device Trade name

Color LCD Monitor, RadiForce RX210

5. Common/Usual Name

Image display system, medical image workstation, image monitor/display, and others

6. Classification Number

Medical displays classified in Class II per 21 CFR 892.2050.

7. Predicate Device

Manufacturer	:	EIZO NANAO CORPORATION
Device Name	:	Color LCD Monitor
Model Name	:	RadiForce R22
510(k) No.	:	K033466

8. Description of Device

RadiForce RX210 is a 54cm (21.3") Color LCD display for medical image viewing. RX210 displays high-definition medical imaging.

9. Intended Use

RadiForce RX210 is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The device is not specified for digital mammography system.

10. Technological Characteristics

RadiForce RX210 is substantially equivalent to R22. RX210 employs the maximum resolution values same as that of R22. Additional product innovations include Digital Uniformity Equalizer (DUE), which enables compensates for luminance non-uniformity. And the brightness improved.

Comparison table of the principal characteristics of 2 devices is shown in the Attachment 1.

Appendix 1: Comparison Table with Predicate Device

Items	R22	RX210
510(k) Number	K033466	Not known
Panel Size and Type	54 cm (21.3") TFT color LCD panel	It is same as the following.
Cabinet Color	Black	It is same as the following.
Pixel Pitch	0.270 x 0.270mm	It is same as the following.
Display colors	1.6777,216 colors	It is same as the following.
Viewing Angles	H: 170°, V: 170°	It is same as the following.
Scanning Frequency (H, V)	Analog:31-94kHz, 49-86Hz Digital:31-76, 59-61Hz (VGA Text:69-71Hz)	Analog:24-100kHz, 49-86Hz Digital:31-100kHz, 59-61Hz (VGA Text:69-71Hz)
Native Resolutions	1600 x 1200 (landscape)	It is same as the following.
Brightness	250 cd/m²	600 cd/m² (Typical)
Contrast Ratio	400: 1 (typical)	600: 1 (typical)
DOT Clock	Analog:202.5MHz Digital:162MHz	Analog:202.5MHz Digital:162MHz
Response Time	50 ms (typical)	25 ms (typical)
Active Display Size (H x V)	432mm x324mm	It is same as the following.
Viewable Image Size	540 mm (21.3") (diagonal)	It is same as the following.
Luminance Calibration	Software (Optional) Photo-sensor (Optional) Protection Panel (Optional)	Software (Optional) Photo-sensor (Optional) Protection Panel (Optional) Digital Uniformity Equalizer
Input Signals	RGB Analogue DVI Standard 1.0	It is same as the following.
Input Terminals	DVI-D 29 pin D-sub mini 15 pin	It is same as the following.
USB Ports / Standard	1 upstream / Rev.1.1	1 upstream, 2 downstream/Standard Rev.2.0
Power	AC100-120V, 200-240V, 50/60Hz	It is same as the following.
Power Management	DVI-DMPM VESA DPMS	It is same as the following.
Dimensions (W x H x D)	With Stand: 472 x 459 mm– 541 x 208.5 mm Without Stand: 472 x 373 x 69 mm	With Stand: 376 x 522.5 mm– 604.5x 208.5 mm Without Stand: 376 x 500 x 92 mm
Certifications & Standards	TUV/GM, CE Medical Device Directive, CB (EN60601-1), cTUVus (UL2601-1, CSA C22.2 No. 601-1), VCCI-B, FCC-B, Canadian ICES-003-B, CCC	TUV/GM, CE Medical Device Directive, CB (EN60601-1), cTUVus (UL60601-1, CSA C22.2 No. 601-1), VCCI-B, FCC-B, Canadian ICES-003-B, CCC

Since the software used in R22 is not changed, refer to the 510(k) Summary of K033466 for the information of calibration software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Hiroaki Hashimoto
Manager of Engineering Management Section
EIZO NANAO Corporation
153 Shimokashiwano, Hakusan
Ishikawa 924-8566
JAPAN

NOV - 9 2006

Re: K063120
Trade/Device Name: Color LCD Monitor, Radiforce RX210
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 2, 2006
Received: October 12, 2006

Dear Mr. Hashimoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Not known K063120

Device Name : Color LCD Monitor, RadiForce RX210

Indications For Use:

RadiForce RX210 is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The device is not specified for digital mammography system.

Prescription Use ✓ ~~AND~~/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063120